Diplomarbeit

Radiologische Nachuntersuchung von 100 Hüfttotalendoprothesen mit Corail® Schaft ohne Kragen und 36 mm Keramik Keramik Gleitpaarung mit durchschnittlich 6,3 Jahren follow-up – Eine retrospektive Studie

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Michael Andreas Pfann

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unter der Anleitung von

OA Dr.med.univ. Werner Maurer-Ertl

OA Priv.-Doz. Dr.med.univ.Dr.scient.med. Lukas Holzer

Univ.-Prof. Dr.med.univ. Andreas Leithner

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Graz, am 15.05.2017 *Michael Pfann eh*

1. Danksagung

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2. Abstract

2.1. Abstract (English)

Background: In 2016 the Corail® cementless hydroxyapatite (HA) coated hip stem celebrated its 30th anniversary. There is limited data on the midterm results with the use of the collarless version of the Corail® stem.

Objectives: In this study we focused on the stem's subsidence and the presence of radiolucent lines, especially in combination with a 36 mm ceramic-on-ceramic (CoC) hard bearing.

Study Design & Methods: This retrospective single center study included 100 total hip replacements (THR) in 94 patients. There were 46 males and 48 females, who underwent THR. The collarless Corail® KS and KHO stems (DePuySynthes Inc., Warsaw, IN, USA) were combined with a Pinnacle® cementless cup (DePuySynthes Inc., Warsaw, IN, USA) and a 36 mm CoC bearing (CeramTec GmbH, Plochingen, Germany). The average age at the time of surgery was 62,0 years (range: 21,0 – 81,0) and the mean Body Mass Index (BMI) was 27,6 (range 18,5 – 45,0). Radiographical analyses were performed independently by two orthopaedic senior surgeons for following parameters: Radiolucent lines (RLL) according to Gruen and Johnston, stress shielding, osteolysis, heterotope ossifications. Biomechanical offset status, leg length, CCD-angle, as well as inclination and anteversion of the cup that were measured by using MediCAD classic®. Hip stem migration was measured with EBRA-FCA® (Einzel-Bild-Röntgen-Analyse-Femoral Component Analysis).

Results: Stress shielding was detected in three cases, osteolysis in one. Brooker heterotopic ossification grade 1 was found in eleven, grade 3 in two cases. Especially zone 1 (39%), 8 (32%) and 14 (18%) according to Gruen and Johnston were affected by radiolucent lines. Leg length discrepancies revealed a mean correction from 3,9 mm preoperatively (range: 0,0 – 20,0) to a mean of 4,3 mm (range: 0,0 – 13,0) postoperatively. The mean preoperative acetabular offset measured 35,7 mm (range: 27,0 – 68,0), the mean postoperative offset 31,7 mm (range: 26,0 – 51,0). The mean preoperative femoral offset changed from 39,1 mm (range: 13,0 – 60,0) to 43,3 mm (range: 30,0 – 55,0) postoperatively. The average CCD-angle measured 125,6° preoperatively (range: 102,3 – 141,4) and changed to

135,0° postoperatively (range: 129,2 – 142,8). The average anteversion of the Pinnacle cup measured 20,2° (range: 9,5 - 28,7) and the mean inclination measured 44,3° (range: 30,0 - 62,6). There was no cup with less than 9,5° of anteversion and no cup with a steeper inclination of 62,6°. The EBRA-FCA® measurement revealed an average stem subsidence of 0,26 mm after six months, 0,34 mm after one year, 0,51 mm after two years, 0,53 mm after four years, 0,46 mm after six and 0,60 mm after 8 years.

Two stems were revised. One due to aseptic loosening of the stem and the second due to biomechanical discrepancy. One patient complaint of a painless and well-functioning squeaking hip joint without index for revision surgery, but regular follow-up intervals are planned. No other adverse events occurred.

Conclusion: The data of this retrospective analysis indicate a stable osseointegration of the cementless hydroxyapatite coated collarless Corail® hip stem despite the use of a challenging large 36 mm hard-on-hard ceramic bearing couple. Subsidence data show less than 0,70 millimeters six years after primary implantation. The obtained results using the collarless Corail® stem with a 36 mm CoC bearing are encouraging with regards to migration and osseointegration of the stem.

2.2. Abstract (German)

Hintergrund: Im Jahr 2016 feierte der zementfreie Hydroxyapatit (HA)-beschichtete Corail® Schaft 30. jähriges Jubiläum. Neben hervorragenden Registerdaten für den Corail® Schaft sind speziell für die kragenlose Schaftversion insbesondere in Kombination mit einer 36 mm Keramik Keramik Gleitpaarung bis dato keine Daten verfügbar.

Ziele: Im Zuge der vorliegenden Diplomarbeit sollte die Schaftmigration mittels EBRA-FCA® Vermessung sowie das Auftreten von radiologisch sichtbaren Lysesäumen im Bereich der Schaftverankerung, speziell für den kragenlosen Corail® Schaft in Verbindung mit einer 36 mm Keramik Keramik Gleitpaarung, erhoben und beurteilt werden.

Studiendesign & Methoden: In diese retrospektive Single-Center-Studie wurden 100 Hüfttotalendoprothesen (HTEP) aufgeteilt auf 94 PatientInnen (46 Männer, 48 Frauen) eingeschlossen. Die kragenlosen Corail® KS und KHO Schäfte (DePuySynthes Inc., Warsaw, IN, USA) wurden mit einer zementfreien Pinnacle® Pfanne (DePuySynthes Inc., Warsaw, IN, USA) und einer 36 mm Keramik Keramik Gleitpaarung (CeramTec GmbH, Plochingen, Germany) kombiniert. Das Durchschnittsalter betrug am Tag der Operation 62,0 Jahre (21,0 – 81,0) und der durchschnittliche BMI lag bei 27,6 (18,5 - 45,0). Die radiologische Analyse wurde von zwei Oberärzten der Orthopädie unabhängig voneinander durchgeführt und beinhaltete folgende Parameter: Lysesäume nach Gruen und Johnston, Stress shielding, Osteolysen und heterotope Ossifikationen. Das acetabuläre und femorale Offset, die Beinlänge, der CCD-Winkel als auch die Inklination und Anteversion der Pfanne wurden mit der Software MediCAD classic® vermessen. Die Migration des Schaftes wurde mittels der Software EBRA-FCA® (Einzel-Bild-Röntgen-Analyse-Femoral Component Analysis) erhoben.

Ergebnisse: Stress shielding trat in drei Fällen auf, Osteolysen in einem Fall. Heterotope Ossifikationen Grad 1 nach Brooker wurden in elf, Grad 3 nach Brooker in zwei Fällen festgestellt. Vor allem in den Gruenzonen 1 (39%), 8 (32%) und 14 (18%) waren Lysesäumen nachweisbar. Die Beinlängendifferenz betrug präoperativ im Durchschnitt 3,9 mm (0,0 – 20,0) und postoperativ durchschnittlich 4,3 mm (0,0 – 13,0). Das mittlere präoperative acetabuläre Offset betrug 35,7 mm

(27,0 – 68,0), das postoperative offset 31,7 mm (26,0 - 51,0). Das mittlere präoperative femorale Offset belief sich auf 39,1 mm (13,0 – 60,0) und änderte sich zu 43,3 mm (30,0 – 55,0) postoperativ. Der CCD-Winkel betrug präoperativ durchschnittlich 125,6° (102,3 – 141,4) und veränderte sich postoperativ zu druchschnittlich 135,0° (129,2 – 142,8). Die mittlere Anteversion der Pinnacle® Pfanne betrug 20,2° (9,5 - 28,7) und die durchschnittliche Inklination belief sich auf 44,3° (30,0 - 62,6). Es war keine Pfanne mit einer Anteversion von weniger als 9,5° und einer Inklination steiler als 62,6° vorhanden. Die EBRA-FCA® Messung zeigte ein durchschnittliches Absinken des Schaftes von 0,26 mm nach sechs Monaten, 0,34 mm nach einem Jahr, 0,51 mm nach zwei Jahren, 0,53 mm nach vier Jahren, 0,46 mm nach sechs Jahren und 0,60 mm nach 8 Jahren.
Zwei HTEP wurden revidiert. Eine infolge aseptischer Lockerung des Schaftes und eine aufgrund von biomechanischer Diskrepanz. Ein Patient berichtete über ein Quietschen des Hüftgelenks, welches allerdings keine Schmerzen verursachte und die Funktion des Gelenks nicht beeinträchtigte. Eine Revisionsoperation wurde nicht indiziert. Regelmäßige Kontrollen sind geplant. Keine anderen unerwünschten Ereignisse traten auf.
Schlussfolgerung: Die Daten dieser retrospektiven Studie zeigen eine stabile Knochenverankerung des kragenlosen zementfreien und HA beschichteten Corail® Schaftes. Dies gilt insbesondere für die Kombination mit einer 36 mm Keramik-Keramik Gleitpaarung. Das Nachsinken des Schaftes betrug weniger als 0,70 mm sechs Jahre nach Primärimplantation. Die erzielten Ergebnisse des kragenlosen Corail® Schaftes mit 36 mm Keramik Keramik Gleitpaarung sind hinsichtlich Migration und Knochenverankerung vielversprechend.

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3. Glossar und Abkürzungen

AP	Anteroposterior
AX	Axial
BMI	Body Mass Index
CCD-angle	Caput-Collum-Diaphyseal-angle
CoC	Ceramic on Ceramic
CoM	Ceramic on Metal
CoP	Ceramic on Polyethylene
EBRA-FCA®	Einzel-Bild-Röntgen-Analyse-Femoral Component Analysis
FU	Follow-up
HA	Hydroxyapatite
HO	Heterotopic Ossification
HTEP	Hüfttotalendoprothese
JPEG	Joint Photographic Experts Group
MoP	Metal on Polyethylene
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
OECD	Organisation for Economic Co-operation and Development
PACS	Picture Archiving and Communication System
PMMA	Polymethylmethacrylat
PO	Pelvis Overview
RSA	Radiostereometric Analysis
SPSS	Statistical Package for Social Science
THR	Total Hip Replacement

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6. Introduction

6.1. Background of the study

Today in 2016, the Corail® hip stem celebrates its 30th anniversary. In 1986, the ARTRO group implanted the first Corail® stem in France [1].
There has been a major increase in the number of total hip replacement (THR) during the last decade in most of the Organisation for Economic Co-operation and Development (OECD) countries [2]. There was not only an increase in the amount of older patients, but also in younger ones (< 65 years) [3]. In 2011, 22.963 THR were implanted in Austria, which indicates about 273 THR per 100.000 inhabitants [2]. Kurtz et al. prognosticate an increase of 174% from 2005 to 2030 for THR in the US [4].
In its early years, the THR suffered from certain setbacks. Inadequate asepsis and fixation of the implant has been huge problems those days [5].
In 1927, William Hey Groves performed a replacement of the femoral head by using an ivory nail [6, 7]. In 1938, Marius Nygaard Smith-Petersen invented a cap made of Vitallium, which was pinned on the femoral head without any other fixation [7, 8]. The next important step in the development of the THR was Philip Wiles' invention in 1938, since he was the first to perform a THR by inserting a pre-formed acetabulum and femoral head consisting of stainless steel. By using screws, the acetabulum was restricted from rotating. A bolt passing through the neck of the femur secured the femoral head [8, 9]. This prosthesis was seen as "the precedent of the modern genre" [8]. The next cornerstone in the development of the THR, was set by Sir John Charnley in 1962. He came up with three new inventions: Firstly, he found the so called „low friction" arthroplasty. Secondly, he utilized the bone cement Polymethylmethacrylat (PMMA) to fix the components in the bone. Thirdly, he used polyethylene with a high density as bearing material [7, 8].
In the following years, there had been a lot of improvements concerning the bearing-systems, the design of the prosthesis, the surgical-techniques as well as the cementless fixation-technique [5].
All these steps gave rise to the fact that the THR is one of the most successful operations of our time. According to Coventry in 1991, THR is the orthopaedic operation of the century [8, 10].

6.2. Aim of the study

The midterm results of the collarless Corail® stem, particularly its subsidence and the presence of radiolucent lines, in combination with the large 36 mm CoC bearing, is the primary aim of the present study.

7. Material and Methods

7.1. Patients

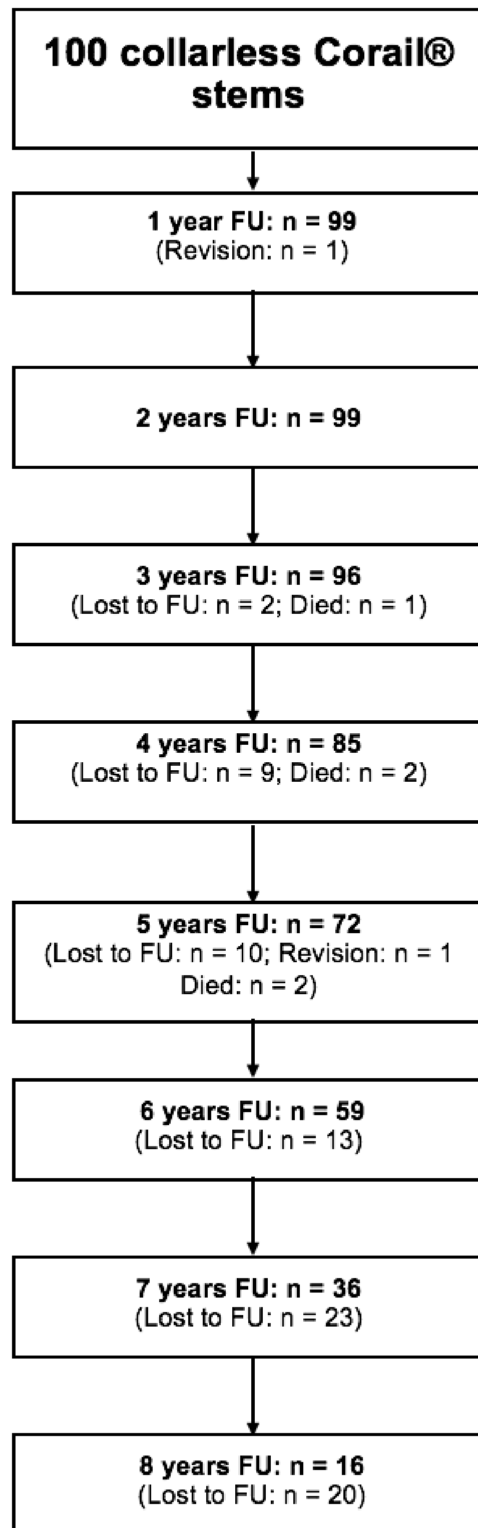


Figure 1: Follow-up flow chart of the collarless Corail® stem

100 THR in 94 patients were included in this study. On the one hand statistical analysis can be performed with this number of THR, respectively statistical significant differences and results can be gathered. On the other hand, there is no comparable study in literature with this number of THR dealing with this topic. From a former study containing 998 THR, which were implanted between 2005 and 2012 at the Medical University of Graz, 100 THR with the collarless Corail® KS or KHO stem and a 36 mm CoC bearing were included. The 100 THR with the longest time of follow-up (FU) and with at least 3 available radiographs were chosen. All 100 THR were performed between January 2006 and April 2009. 5 patients died during the time of follow-up and several were lost to FU (Fig. 1). The mean follow-up was 75,4 months (6,3 years) with a range from 1 to 125 months.

Table 1: Demographic data of the study population

	Female	Male	Total
Sex	48	46	94
Age (mean)	64,6	59,3	62,0
BMI (mean)	27,7	27,6	27,6

The patients mean age at the day of operation was 62,0 years with a range from 21,0 to 81,0 years. The average age of all female patients was 64,6 years with a range from 34,0 to 81,0 years. The mean age of all male patients was 59,3 years with a range from 21,0 to 81,0 years.

The mean BMI at the time of operation was 27,6 with a range from 18,5 to 44,6. The mean female BMI was 27,7 (standard deviation: 4,39) with a range from 18,5 to 44,6. The mean male BMI was 27,6 (standard deviation: 4,06) with a range from 19,3 to 37,9.

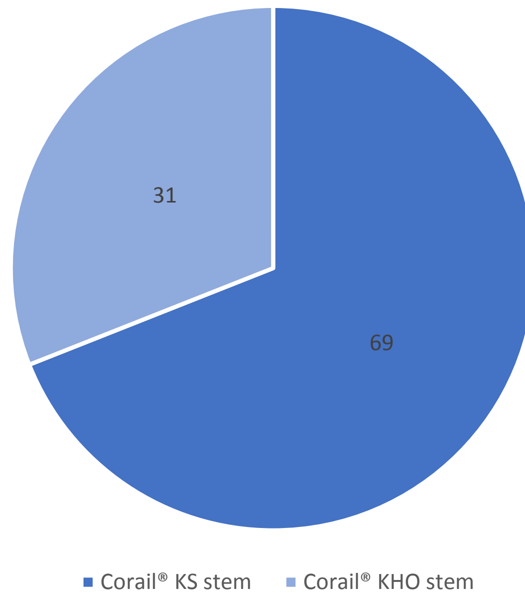
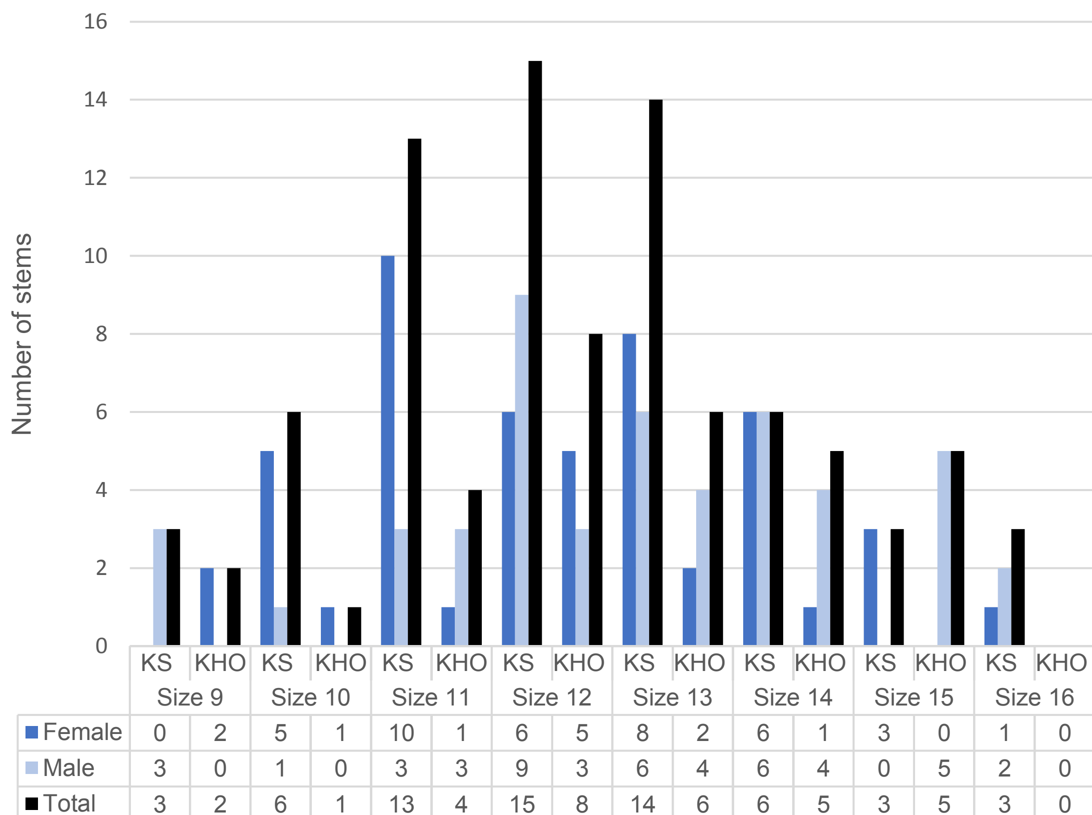


Figure 2: Distribution of the collarless Corail® KS and KHO stem

The collarless Corail® standard offset (KS) stem was used in 69 THR, in 39 women and in 30 men. The Corail® high offset (KHO) stem, which is also collarless was used in 31 cases, in 12 women and in 19 men.



	Size 9		Size 10		Size 11		Size 12		Size 13		Size 14		Size 15		Size 16	
	KS	KHO	KS	KHO	KS	KHO	KS	KHO	KS	KHO	KS	KHO	KS	KHO	KS	KHO
Female	0	2	5	1	10	1	6	5	8	2	6	1	3	0	1	0
Male	3	0	1	0	3	3	9	3	6	4	6	4	0	5	2	0
Total	3	2	6	1	13	4	15	8	14	6	6	5	3	5	3	0

Figure 3: Distribution of the different stem sizes and types

Figure 3 reveals how often which stem size (9 to 16) and type (KS or KHO) was used. The most common stem size in the female population was size 11 and 12 with each 11 cases (each 21,6% of all stems, which were implanted in the female population), followed by size 13 with 10 cases (19,6%). The most utilized stem size in the male population was stem size 12 with 12 cases (24,5% of all stems, which were implanted in the male population), followed by stem size 13 and 14 with 10 cases each (20,4%).

Table 2: Indications for THR

Indications	Female	Male	Total
Primary osteoarthritis	43	32	75
Avascular necrosis	3	14	17
Hip dysplasia	3	1	4
Posttraumatic osteoarthritis	1	1	2
Coxitis	1	0	1
Girdlestone	0	1	1

In 75 cases (75%, female: 43, male: 32) primary osteoarthritis was the indication. The second most common diagnosis was the avascular necrosis in 17 cases (17%, female: 3, male 14), which was almost 5 times higher in the male than in the female population. Hip dysplasia was the indication in 4 cases (4%, female: 3, male: 1), posttraumatic osteoarthritis in 2 cases (2%, female: 1, male: 1), coxitis in 1 case (1%, female: 1, male: 0) and the girdlestone arthroplasty in 1 case (1%, female: 0, male: 1).

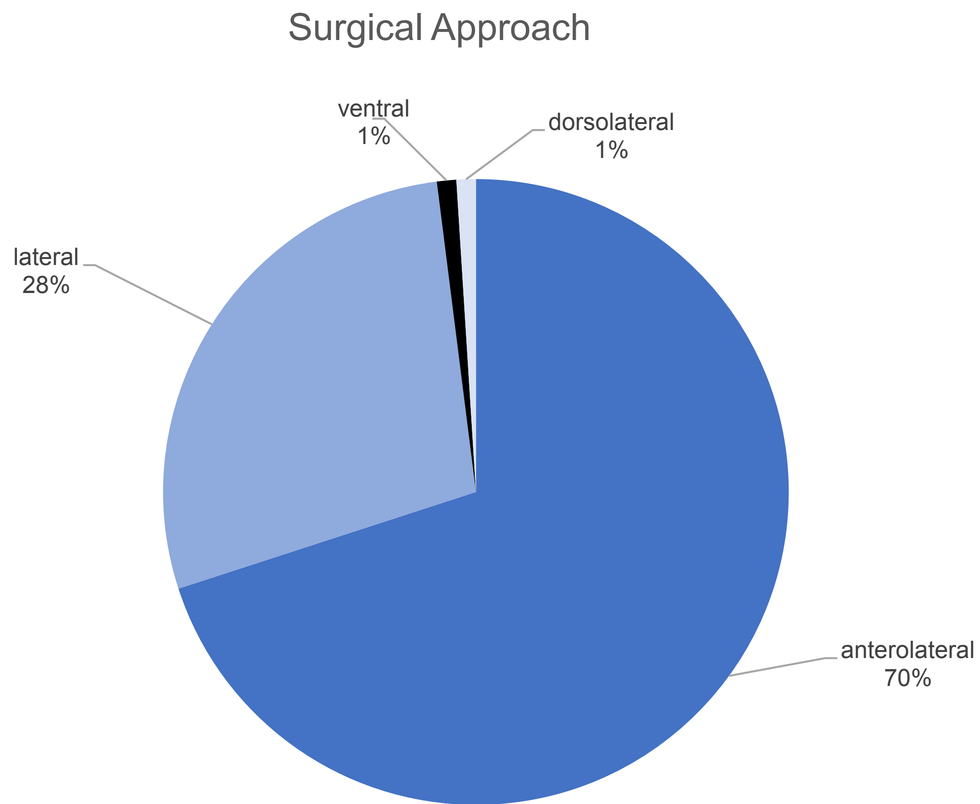


Figure 4: Surgical approach

With a percentage of 70 (70 cases), the anterolateral approach was the most common one. In 28% (28 cases) the lateral approach was the second most common one, followed by the ventral and dorsolateral one with each 1% (1 case each).

Table 3: Intraoperative complications

Intraoperative complications	Female	Male	Total
Greater trochanteric fracture	4	1	5
Femoral fissure	1	1	2

Intraoperative complications occurred in 7 cases (in 7% of all THR in this study). The most abundant complication was the greater trochanteric fracture in 5 cases. Femoral fissure arose in 2 cases.

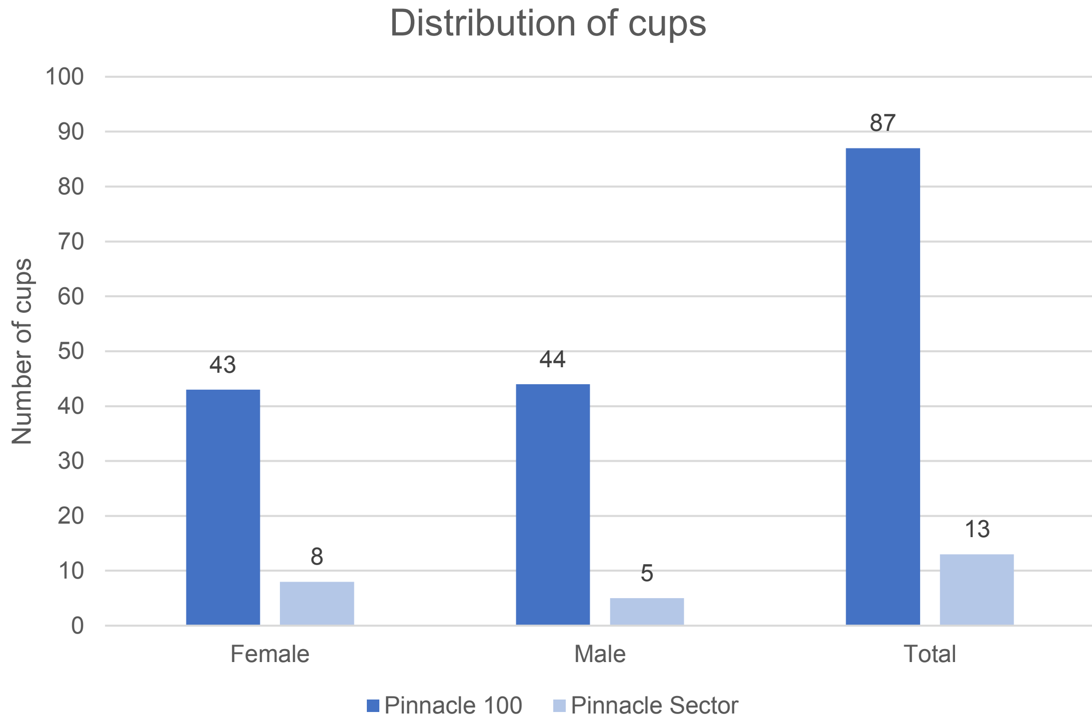


Figure 5: Cup types

The Pinnacle® 100 cup is utilized in 87 cases (87%, female: 43, male: 44), the Pinnacle® Sector cup in 13 cases (13%, female: 8, male: 5).
The most common cup size in the female population was size 52 (49% of all cups, which were implanted in the female population), in the male size 54 (36,7% of all cups, which were implanted in the male population).

Table 4: Cup sizes

Cup size	52	54	56	58	60	62
Female	25	14	8	3	1	0
Male	10	18	7	8	3	3
Total	35	32	15	11	4	3

7.2. The Corail® stem (DePuySynthes Inc., Warsaw, IN, USA)

The first Corail® stem was implanted 30 years ago in France and has been implanted about 1,6 million times to this date [1, 11].
The Corail® stem is a double-tapered, titan alloyed (TiAl6V4), hydroxyapatite (HA) coated cementless stem. Its cross section is quadrilateral. The proximal part is extended cuneiform in the sagittal and coronal plane to archive three dimensional stabilization in the metaphyseal section. The distal part is tapered to create rigidity and to avoid an obstruction of the medullary canal. Macrotextural features, like horizontal and vertical grooves, increase the primary mechanical stability, which can be improved further by an optional collar [12, 13, 14].
In this study only the collarless Corail® standard offset (KS) stem (Fig. 8) and the Corail® high offset (KHO) stem (Fig. 9) were applied.
Further stem options are the collared Corail® standard offset stem, the Corail® Coxa Vara, the Corail Dysplasia and the Corail® cemented stem, which were not included in this study [15].
The whole stem is coated with HA to avoid the release of metal ions, to arrange a maximum of osseointegration at the prosthesis-bone-interface and to prohibit the development of a fibrous membrane all round the distal area of the stem. By using an atmospheric plasma spray procedure, the HA coating is applied. The ceramic layer’s thickness amounts to 150 µm [12, 13].

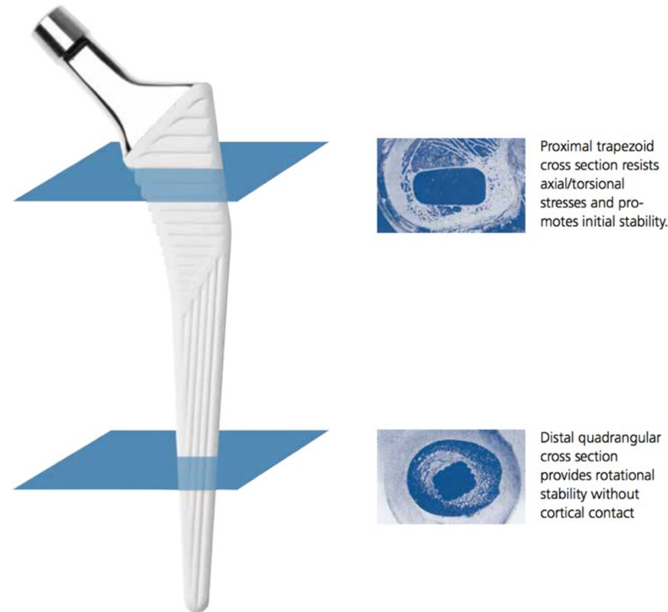


Figure 6: The collarless Corail® stem and its proximal and distal cross section through the femur, from https://2584137723734143384.s3.amazonaws.com/pdf/2013/6/Corail_Design_Rationale_and_Surg_Tech.pdf accessed 2017/01/18

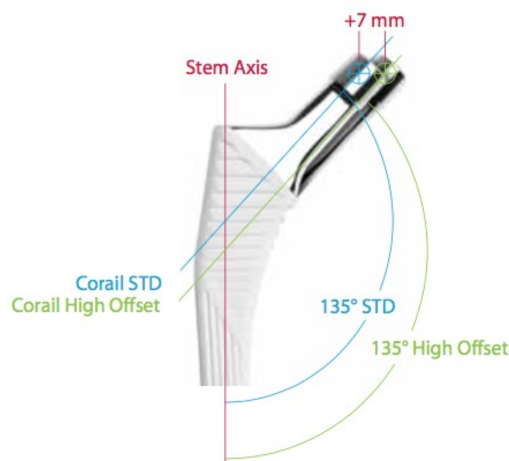


Figure 7: The Corail® standard offset (STD=KS) and high offset (KHO) stem. The high offset option ads 7 mm of direct lateralization to reconstruct hip biomechanics in a broader variety of patients, from https://2584137723734143384.s3.amazonaws.com/pdf/2013/6/Corail_Design_Rationale_and_Surg_Tech.pdf accessed 2017/01/18

Figure 8: The Corail® Standard offset (KS) stem, 135° neck angle, available in sizes 8 - 20, from http://www.corailpinnacle.net/sites/default/files/2016-04/corail-product-rationale-and-surgical-technique.pdf accessed 2017/01/18

Figure 9: The Corail® high offset (KHO) stem, 135° neck angle, always collarless, available in sizes 9 – 20, from http://www.corailpinnacle.net/sites/default/files/2016-04/corail-product-rationale-and-surgical-technique.pdf accessed 2017/01/18

7.3. The Pinnacle® cup (DePuySynthes Inc., Warsaw, IN, USA)

The Pinnacle® cup system is a modular cup system with a considerable variety of different cup and bearing options. Moreover, the cup possesses both, biological and mechanical fixation possibilities [16]. Introduced in 2000, the Pinnacle® cup was implanted more than two million times until the year 2015 [17].

This study made use of the pinnacle® 100 (Fig. 10) and the pinnacle® sector (Fig. 11) cup. Both are titanium alloyed, porous coated, hemispherical cementless press-fit cups. Due to the biological fixation, the porous coating, which consists of “titanium sintered metal beads“, leads to bone ingrowth [18, p5]. The apical hole serves different purposes. On the one hand it is applied for impaction, on the other hand for viewing to guarantee complete seating of the cup [18].

The Pinnacle® cup is divided into two regions: The “dome region”, which includes 140° of the inner cup and the so called Variable Interface Prosthesis (VIP) taper, which reaches to the cup’s fringe (Fig. 12). The VIP taper causes an extended modularity, which results in an enhanced performance for polyethylene and in supporting hard bearing inserts, like ceramic or metal, without any interference of quality [16]. Beside the two cup types, which were used In this study, there are further cup options: The Pinnacle® Multi-Hole cup with 8 to 12 screw holes, the Pinnacle® 300 cup with additional spikes, the Pinnacle® Bantam cup for shorter patients or smaller acetabular dimensions and two revision cups, the Pinnacle® Revision Standard Profile cup and the Pinnacle® Revision Deep Profile DPx [18].

Figure 10: The Pinnacle® 100 cup, available in sizes 48 – 60 [16], from http://www.corailpinnacle.net/sites/default/files/100.jpg accessed 2017/01/04

Figure 11: The Pinnacle® sector cup, three holes for additional fixation, available in sizes 48 to 66 [16], from http://www.corailpinnacle.net/sites/default/files/sector.jpg accessed 2017/01/04

Figure 12: Inside view of the Pinnacle® cup. The white arrow marks the VIP taper, from http://www.pei.ie/PEI/media/PEI-media/PDFs/PDFs_Ortho/PDFs_Ortho_Products/PDFs_Ortho_Products_DePuy/Pinnacle-Design-Rationale.pdf accessed 2017/01/18

7.4. The ceramic on ceramic, 36 mm bearing (CeramTec GmbH, Plochingen, Germany)

In this study only ceramic ball heads (BIOLOX® delta) with a diameter of 36 mm and ceramic cup inserts (BIOLOX® delta) with an inside diameter of 36 mm were used.

Aluminum-oxide particle, zirconium-oxide particle, which absorb impacting forces and crack-stopping platelets form the special microstructure of the BIOLOX® delta ball heads and cup inserts [19].

Figure 13: The BIOLOX® delta ball heads, from https://www.linkorthopaedics.com/de/fuer-den-arzt/produkte/huefte/prothesenkoepfe/keramik-koepfe/ accessed 2017/01/04

7.5. X-ray analysis

The x-ray analysis was based on standing pelvis overview (PO), lying anteroposterior (AP) and lying axial (AX) radiographs. There were at least two preoperative radiographs (one AP, one PO) and various postoperative (AP, AX and PO) from every patient during the time of follow up. The x-rays were downloaded in PACS (Picture Archiving and Communication System, Siemens Healthcare GmbH, Erlangen, Germany) and saved as JPEG (Joint Photographic Experts Group) data format through Microsoft Paint version 6.1 (Microsoft Corporation, Redmond, WA, USA). However, PACS could only provide all the required x-rays for 47 out of 94 patients. For the remaining 47 patients the needed radiographs only existed in analogue form and therefore had to be scanned with a x-ray scanner (VIDAR Sierra Plus Scanner, VIDAR Systems Corporation, Herndon, VA, USA) (Fig. 14). After scanning, the X-rays were equally saved in JPEG data format.

Figure 14: VIDAR Sierra Plus scanner, from http://www.jzimaging.com/IMAGES/Product%20Informaton/Vidar/Pics/sierraproduct.gif accessed 2017/01/05

7.5.1. Heterotopic ossification (HO)

Heterotopic ossification describes the existence of bone in soft tissue, where bone usually does not occur. Among others, people with a shortly performed THR are at high risk for HO [20].

Significant disorders in function can be the consequence of higher grades of HO. However pursuant to T.N. Board, HO is admittedly common but in most cases there won't occur any relevant symptoms [21]. The incidence adds up to 21% after 6 months postoperatively according to Brooker [22]. In other studies the incidence was stated between 5 to 90%, but only 3 to 7 %, which conform with Brooker Grade 3 and 4, are clinically relevant [21]. NSAIDs and radiotherapy are used for the HO treatment, but conforming to T.N. Board et al. there is no indication to perform a prophylactic therapy after a routine THR [21]. In 1973 Brooker et al. invented a grading system, which contains four degrees of severity [22]. For evaluation, AP and AX radiographs were utilized.

Table 5: Classification to Brooker et al. [22]

Class 1	Existence of bone islands inside the soft tissue around the hip
Class 2	Space between proximal femur and pelvis is reduced by bone spurs to ≥ 1 centimetre
Class 3	Space between proximal femur and pelvis is reduced by bone spurs to < 1 centimetre
Class 4	Ankylosis of the hip joint

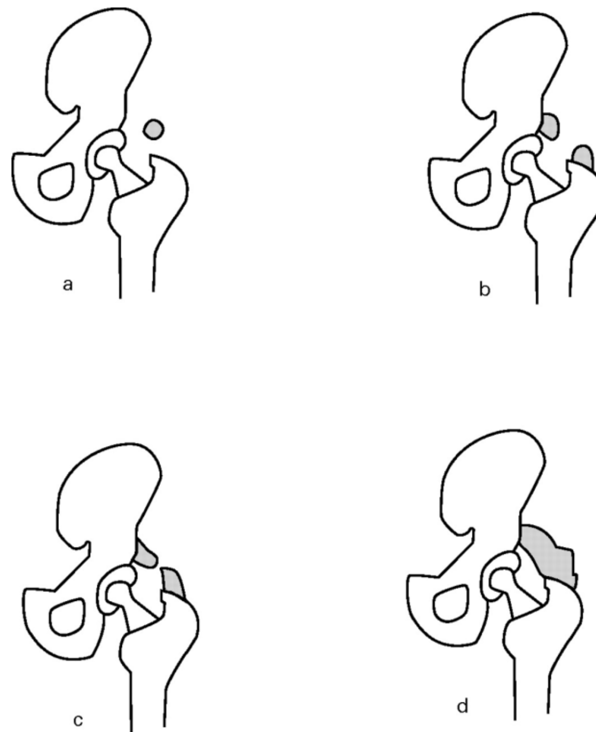


Figure 15: This figure illustrates the classification to Brooker et al.: a= class 1, b= class 2, c= class 3, d= class 4, from T.N. Board et al. J Bone Joint Surg Br. 2007 (21)

7.5.2. Radiolucent lines according to Gruen and Johnston

In 1979, Gruen et al. invented a method in order to give a detailed view of where radiolucent lines occur at the bone-implant interface. Therefore, they divided the prosthesis' stem in 7 zones (Fig. 18). This procedure was used for AP radiographs [23]. Some years later in 1990, Johnston et al. added another 7 zones, 8 to 14, which work to the same principles as the original zones of Gruen. However, they were used for AX radiographs (Fig. 18) [24]. AP and AX radiographs were utilized for evaluation.

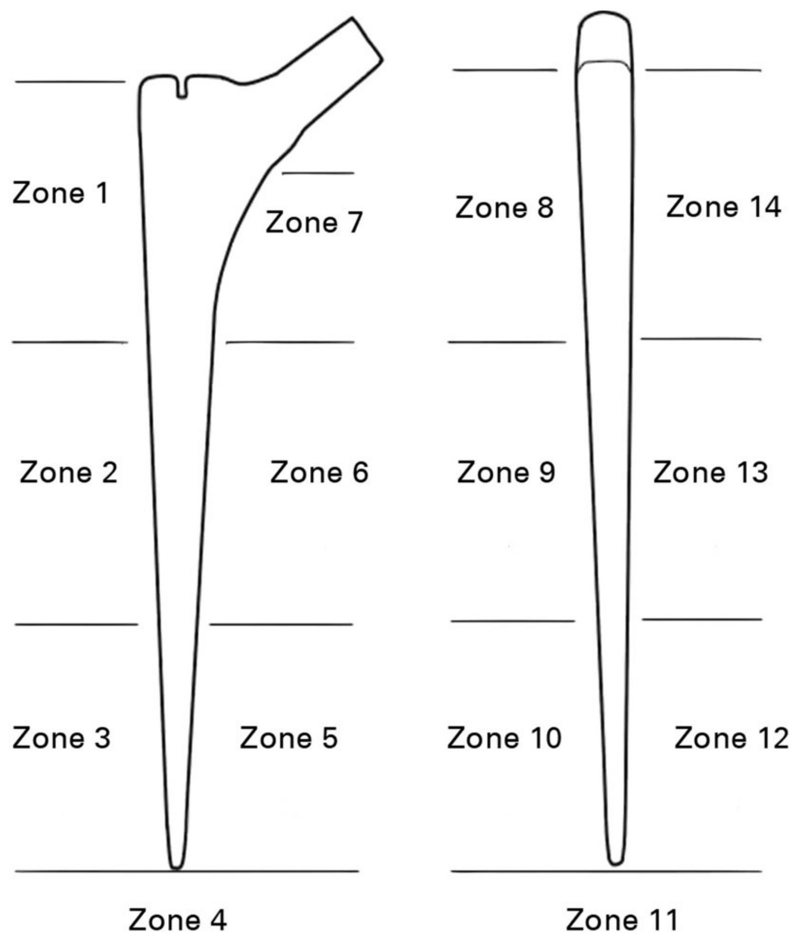


Figure 16: Classification of the stem in 14 zones according to Gruen and Johnston, from http://www.bjj.boneandjoint.org.uk/content/90-B/1/16 accessed 2017/01/06

7.5.3. Stress shielding

Stress shielding implies the bone's tendency to atrophy under mechanical unloading grounded on the principles of Wolff's Law [25].
By performing a THR the stresses and strains, which appear in the bone, alter in comparison to the preoperative circumstances. As a result, the bone changes its shape and internal structure organization due to the different force effect. After the implantation two alterations arise: The hip joint load now includes the implant bone interface, instead of moving downwards through the metaphyseal trabecular structure and the cortex. The load is now shared between stem and bone whereas preoperatively it was solely carried by the bone. This is referred to as load sharing and leads to stress shielding. The stem protects the bone from stress, which causes a remodelling of the bone. The bone resorbs in order to adapt to the new circumstances [26].
On the one hand the prosthesis leads to bone resorption in areas, which now bear less weight and on the other hand increases the bone density in areas where the prosthesis is in contact with the bone [27].
For evaluation, AP and AX radiographs were applied.

7.5.4. Irregular periprosthetic bone resorption (osteolysis)

Periprosthetic osteolysis is a severe medium and long term complication of the THR [28]. Extended osteolysis adds to the most difficult problems correlated with THR [25]. Prosthesis loosening and periprosthetic fracture can be the result, even though osteolysis often remains asymptomatic [28].
Osteolysis can occur adjoining to the acetabular and the femoral part of the prosthesis [25]. The presence of wear, especially the wear of ultrahigh molecular weight polyethylene, as reported by H. Kröger, is very important to the development of osteolysis. However, according to Betty J. Manaster, it seems, that the particle size is more crucial to the formation of osteolysis than the composition.

Multinucleated giant cells and macrophages absorb small particles. This could finally give rise to osteolysis [25, 27].
CoC bearings are supposed to have very low wear rates in comparison to other bearing materials. James D'Antonia et al. performed a study, which compared CoC to metal-on-polyethylene (MoP) bearings in relation to survivorship. According to their findings, osteolysis occurred in non of the CoC bearings at 10 years of follow-up, though in 26% of the MoP bearings in the same time range [29]. AP and AX radiographs were applied in order to evaluate, whether osteolysis occurred.

7.6. MediCAD classic® (Hectec GmbH, Altdorf, Germany)

By using the software MediCAD classic® version 3.50.2.1, the leg length discrepancy, the acetabular- and femoral offset, the CCD-angle as well as the anteversion and inclination of the cup can be measured. Therefore, you need one pre- and one postoperative PO. In addition, The CCD-angle and the femoral offset were measured in pre- and postoperative AP radiographs, since in this kind of x-ray, the whole stem of the prosthesis and a bigger part of the femur is displayed, which leads to a more precise result of the CCD-angle and the femoral offset.

7.6.1. Scanning and converting

As already mentioned, all analogue- as well as all digital radiographs were converted and stored into JPEG format.

7.6.2. Measurement

Measurement of the postoperative PO radiograph

At first, the prosthetic head, which is always 36 mm in diameter, is scaled, since the software needs a benchmark in order to measure the following points and lines.

1. Midpoint of the prosthetic head: Setting for at least 3 points at the margin of the prosthetic head. The midpoint of the head occurs in the radiograph (Fig. 17, number 1).
2. Femoral offset: Placing four points at the outmost point of the cortical bone by drawing two lines across the femur. The software calculates a line, which pulls through the femoral stem in vertical direction. This line is connected to a horizontal line with the previously computed midpoint of the prosthetic head. After that, the value of the femoral offset appears (Fig. 17, number 2).
3. Reference line: Drawing a line from the trochanter minor of the one side, to the trochanter minor of the other side. You have to find exactly the same anatomical structure on both sides to receive a precise result (Fig. 17, number 3).
4. Acetabular offset: Connecting the central point of the acetabulum, which is also the midpoint of the prosthetic head, with the pelvic teardrop figure (Fig. 17, number 4).
5. Leg length discrepancy: Setting two lines from the pelvic teardrop figure of both sides to the radiographs' margin. In this case the leg length discrepancy is +7 mm (Fig. 17, number 5). In this radiograph you see "Beinlängendifferenz: 4mm" which is the hip length discrepancy and not the leg length discrepancy.
6. CCD-angle: Placing four points at the outmost point of the cortical bone by drawing two lines across the femur. The software calculates a vertical line, which pulls the femur in vertical direction (Fig. 17, number 6). After that, you choose "SHA nach M.E. Müller" in the settings and place a circle around the prosthetic head. You set two crosses at exact these points, where the circle

traverses the neck of the prosthesis. The CCD-angle appears in the radiograph (Fig. 17, number 7).

7. Anteversion and Inclination: Setting a reference line from the pelvic teardrop figure of the one side to the other (Fig. 17, number 8). Next, you set a line between these points of the prosthetic cup with the broadest diameter. An elliptical structure appears, which has to be linked with the distal part of the cup (Fig.17, number 9).

Figure 17: Postoperative PO, measured with the MediCAD classic® software

Measurement of the preoperative PO radiograph

The measurement remains mostly the same, however there are several differences in comparison to the postoperative measurement:

1. The software needs a benchmark in order to measure all points and lines, as mentioned before. Therefore, the postoperative PO is utilized for scaling the non-operated femoral head. This diameter is used for scaling the femoral head of the preoperative PO.

2. Acetabular offset: Connecting the central point of the acetabulum, which often differs from the midpoint of the femoral head, with the pelvic teardrop figure.
3. Anteversion and Inclination are not measured.

<u>Measurement of the pre- and postoperative AP radiograph</u>

The femoral offset and the CCD-angle are measured similarly, as stated above. As already mentioned before, the results are more precise, since the whole prosthetic stem and a bigger part of the femur are visible on the radiograph, in contrast to the PO.

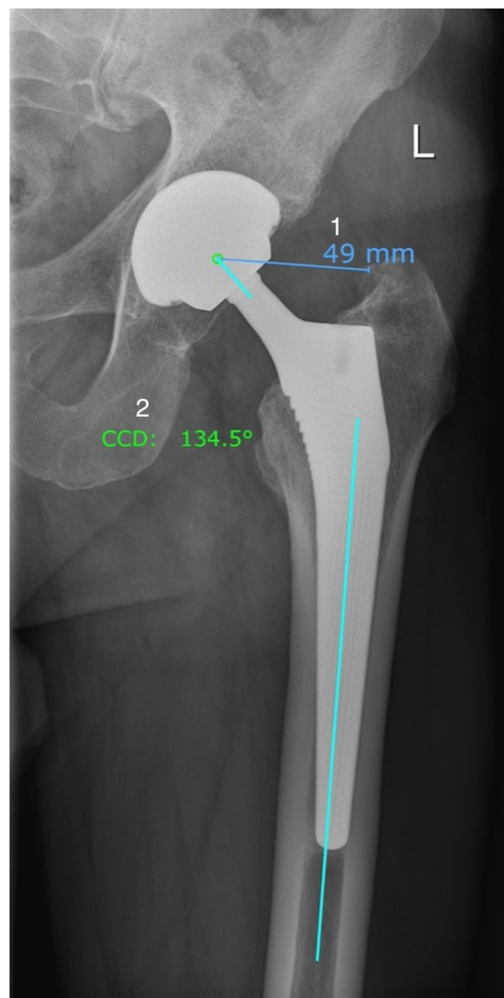


Figure 18: Postoperative AP radiograph, femoral offset (1) and CCD-angle (2) measured with the MediCAD classic® software

7.7. EBRA-FCA (University of Innsbruck, Institute for Basic Sciences in Engineering Unit Geometry and CAD, Austria)

The long-term clinical outcome can be prognosticated by an early measurement of the stem's migration [30]. According to Biedermann et al. “early migration can predict late aseptic failure of the prosthesis” [31].

By using EBRA-FCA® version 1.0, the migration of the prosthetic stem can be determined. For measurement, the software needs at least three AP radiographs from each patient.

Apart from the EBRA-FCA® software, there is the EBRA-Cup® software, which can determine the migration of the acetabular component.

The accuracy of EBRA-FCA® is cited better than +/-1,5 mm. Pursuant to Biedermann et al. the results, which were attained with this procedure are positive [32]. EBRA-FCA® can detect migration over 1 mm with a sensitivity of 78% and a specificity of 100% [32].

This implies that every stem, which did not migrate, is detected, whereas only 78% of all stems, which did migrate are detected.

Consequently, EBRA-FCA® underestimates the stem's migration [32].

By using three parameters, the comparability between pairs of radiographs is evaluated (Fig. 19). The software approves only radiographs inside “chosen limits” [32].

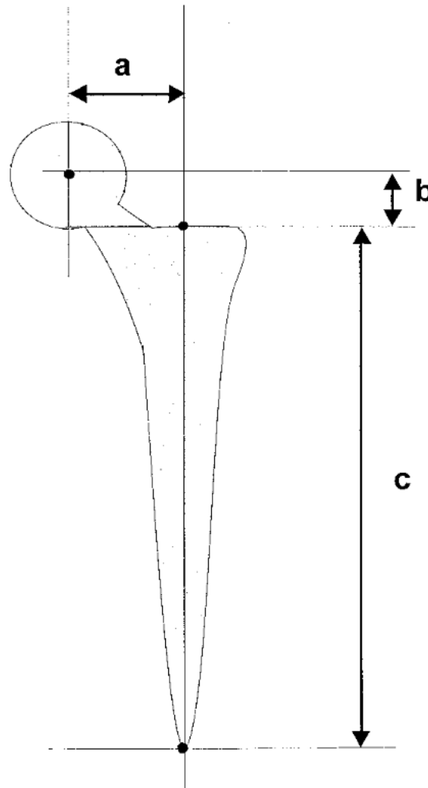


Figure 19: The three parameters to evaluate the comparability. a: Horizontal distance between the centre of prosthetic head and the shoulder point, b: Vertical distance between the centre of prosthetic head and the shoulder point, c: Distance between shoulder point and tip of the prosthesis, from R. Biedermann et al. J Bone Joint Surg Br 1999 [32]

In addition to EBRA-FCA®, there are a couple of other methods in order to measure migration. With an accuracy of 0,2 mm the Radiostereometric analysis (RSA) is the most reliable method. However, you need prospective planning, stereo-radiographs and the implantation of tantalum markers, which makes this method rather work-intensive [30]. Furthermore, there are some procedures, which are easier to run and only depend on conventional radiographs. Still, they posses a lower accuracy [31]. EBRA-FCA® might not possess the best accuracy, but it is enough to evaluate the stability of the stem [32]. The measurement can be performed without any great effort. It is applied postoperatively and only AP radiographs are required [30].

7.7.1. Scanning and converting

As already mentioned, all analogue as well as all digital radiographs were converted and stored into JPEG format.

7.7.2. Measurement

Basically, you have to set points and lines at designated anatomical structures. The difficult part is to find typical anatomical reference points in each radiograph of one patient, in order to get a commensurability as high as possible to ensure a precise result. These reference lines always need to be the same for one patient, but can differ from one patient to another. The measurement is structured in the following way:

First of all, after starting the software and choosing the respective AP radiograph, first- and surname, as well as the date of the x-ray, the patients-ID, the diameter of the prosthesis' head and the file name have to be entered into a provided mask.

1. Measurement of the prosthetic head by setting three points for a minimum, (Fig. 20, number 1).
2. Placing two lines to the lateral and medial side of the stem. The software calculates a line and draws it exactly through the middle of the stem (Fig. 20, number 2)
3. Setting the so called "shoulder point", which is placed exactly at the point, where the prior measured line (Fig. 20, number 2) leaves the stem into the bone (Fig. 20, number 3).
4. Placing a horizontal line through the trochanter major (Fig. 20, number 4). It is crucial to set this line at exact the same anatomical reference point in all radiographs of one patient, in order to guarantee precise results.
5. Positioning two lines to the upper and lower margin of the trochanter minor (Fig. 20, number 5).
6. Placing a horizontal line to the tip of the prosthesis (Fig. 20, number 6). Three horizontal lines appear and pull through the stem (Fig. 20, number 7).

7. The last step is to place the “8 points” at the outmost points of the cortical bone, where the four horizontal lines (Fig. 20, number 6, 7) traverse the cortical bone (Fig. 20, number 8).

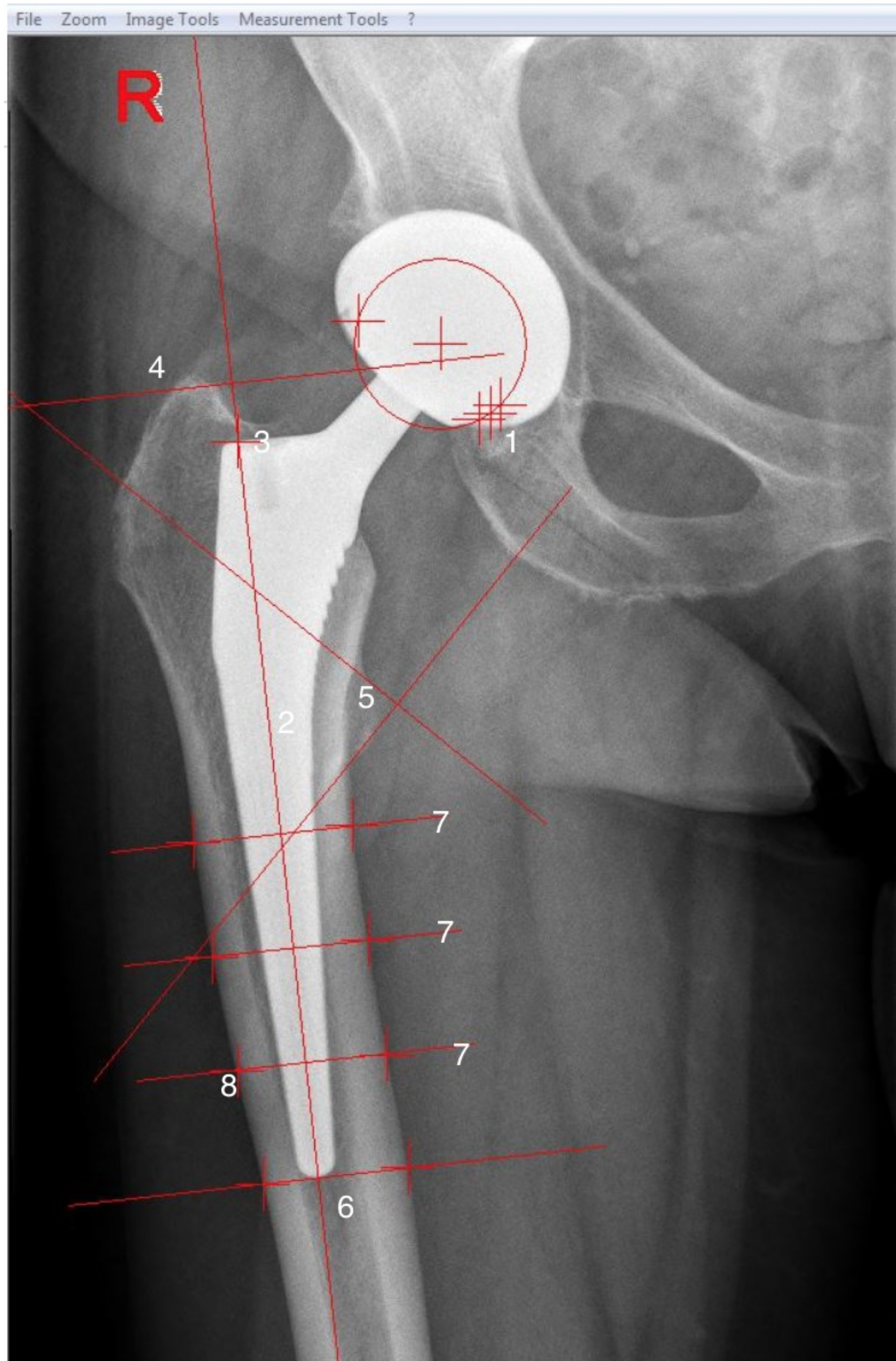


Figure 20: Reference points and lines of EBRA-FCA® measurement

Every measurement has to be saved by “write data”. The data-file contains every measured radiograph of one patient. Therefore, there is one data-file for every patient in this study. In this case, the data-file comprise five radiographs (Fig. 21).

```
"-------> EBRA-FCA 2002  File: BöMa101.fca",#2016-09-13#
"Bö","Ma","101"
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"side of replacement","R","factor-head",2.8402249852623,"factor-stem",1
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"valgus-varus (degrees)",-1.15075595230949,"subsidence",155.995095082714,-7.89439850418312,117.298226171581,-46.5912674153165
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```

Figure 21: The data-file of one patient. This particular file comprises the information of five radiographs

After finishing all measurements of one patient you start the software FcaGraf2011 (Version 1.0, University of Innsbruck, Institute for Basic Sciences in Engineering Unit Geometry and CAD, Austria) and choose the patient’s data-file (Fig. 22). You receive information including the number of radiographs, period of observation and the side of replacement.

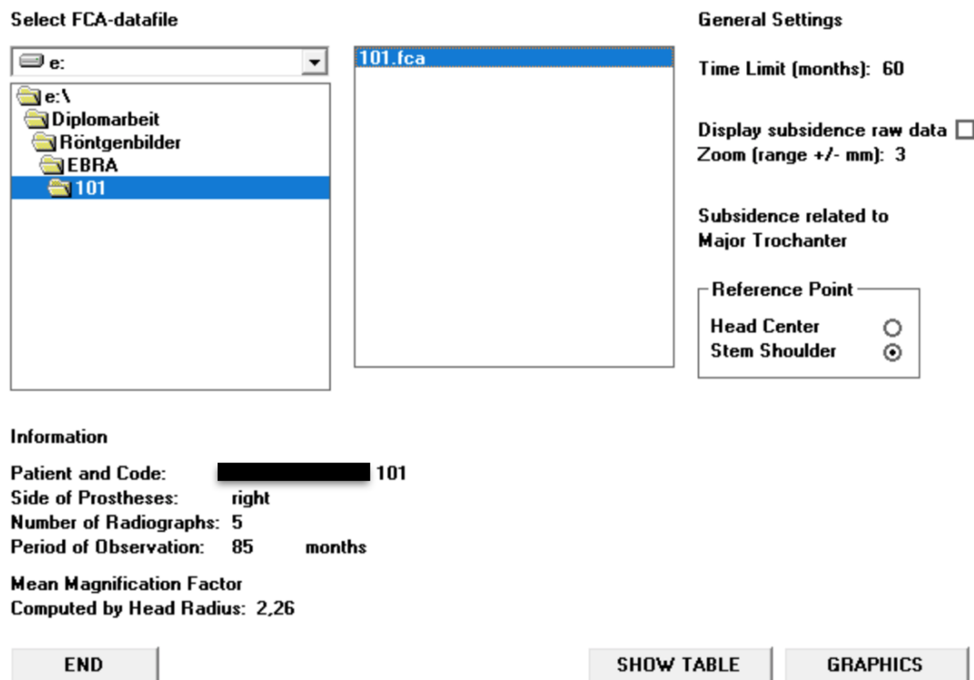

Figure 22: The main menu of FcaGraf2011. Among others, you obtain information about the period of observation or the number of radiographs

The results of the measurement can either be viewed in tabular-, (Fig. 23) or in graphical form (Fig. 24). Both provide information about the period of observation, the time between the operation and the exposure date of every single radiograph. Moreover, they transfer information about the medial and lateral distances between the prosthesis and the bone margin, the angle between stem and bone and finally about the subsidence.

EBRA / FCA - GRAPHICS 2008 TABLE

PATIENT: [redacted] / SIDE OF REPLACEMENT: right
TOTAL NUMBER OF X-RAYS: 5 PERIOD OF OBSERVATION: 85 months
TIME LIMIT: 60 months Subsidence related to MajorTroch. / Shoulder
Magnification computed by head radius (individ.)

FCA - PARAMETERS WITH DIAGRAM-DISCONNECTION-FLAG (0/1)
(dots instead of values mark incomparable radiographs)

months	flag	medial distances 1-4				lateral distances 5-8				angle	Subsidence stem/bone
0	0	00,0	00,0	00,0	00,0	00,0	00,0	00,0	00,0	00,0	00,0
28	0	-00,1	-00,3	00,0	00,1	00,4	00,0	-00,1	-00,2	-00,3	-00,5
52	0	-00,2	-00,2	00,0	00,2	00,8	00,3	00,0	-00,3	-00,4	-00,5
64	0	-00,2	-00,1	-00,1	00,1	00,7	00,3	-00,1	-00,3	-00,4	-00,3
85	1	-00,2	00,1	00,0	00,1	01,2	00,8	00,1	-00,4	-00,6	00,1

<< FILE MENUE PRINT TABLE WRITE FILE (*.NUM)

Figure 23: Tabular form of the results

Explanation:

- The first column mirrors the time between the operation and the exposure date of every single radiograph in months.
- The second column reveals the "flag". Flag "0" implies, that the x-ray is compatible with the radiograph before. The last x-ray of a series is labelled with Flag "1". Also radiographs, which are not compatible with the previous x-rays, are marked with Flag "1".
- In the last column you receive information about the subsidence.

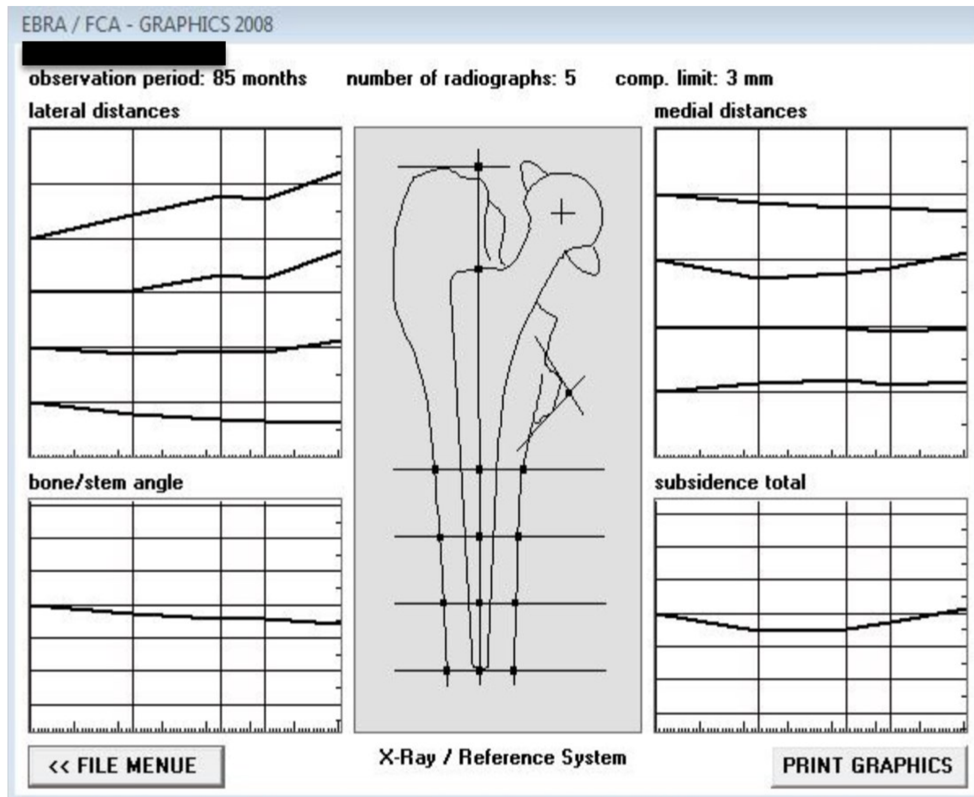

Figure 24: Graphical form of the results

<u>Explanation:</u>

- The diagram on the right hand corner illustrates the subsidence in relation to the time of observation.
- The x-axis reveals the timeline of the radiographs. The smallest vertical lines represent one month, the midsize lines 12 months and the lines, which cross the whole diagram symbolize the exposure date of every single radiograph.
- The y-axis illustrates the migration. The distance between two short horizontal lines as well as between the lines, which cross the entire diagram amounts to 1 mm of subsidence.

The software compares all x-rays of one patient. If one radiograph does not fit into the series of one patient, it is excluded from the measurement. A certain compatibility has to be given to obtain a result as precise as possible. To provide these same you have to choose between 1 to 4 mm of compatibility. It is recommended to choose 3 or 4 mm, otherwise there would be a major increase of non-compatible radiographs.

Due to the fact, that the radiographs of all patients differ with regard to the date of recording, groups were created to achieve comparability. All radiographs, which were taken between month 1 and 6 after implantation, were summarized to group “0,5 years”. All x-rays with the recording date between 1 and 12 months after implantation were summarized to group “1 year”, all radiographs with the exposure date between 13 and 24 months were summed up to group “2 years” and so forth (Table 7).

7.8. Statistics

The Kaplan-Meier survival curve was utilized in this study to reveal the implant survival. Therefore, the Statistical Package for Social Science (SPSS) version 23 software (SPSS Inc., Chicago, IL, USA) was used. Furthermore, a descriptive statistic was applied.

7.9. Ethical review

The study was approved by the ethics committee of the Medical University of Graz. The EK-Number of this Study: 29-366 ex 16/17.

8. Results

8.1. Clinical assessment

100 THR in 94 patients were performed and were afterwards evaluated during a mean follow-up of 6,3 years. Two revision surgeries had to be performed during this time. One, because of aseptic loosening of the stem and the second due to biomechanical discrepancy. One patient complaint of a painless and well-functioning squeaking hip joint without index for revision surgery.

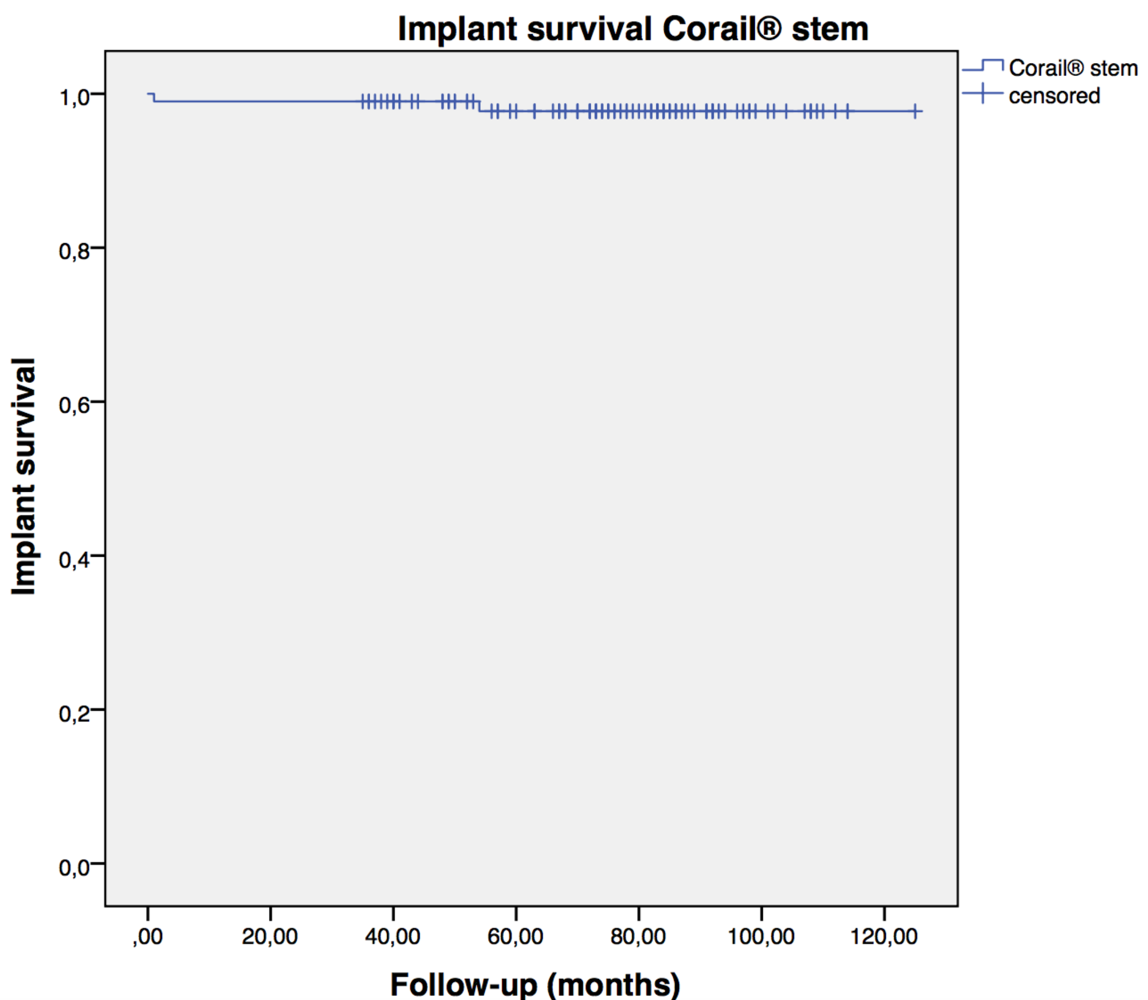

Figure 25: Implant survival for any reason for revision

The Kaplan-Meier curve revealed an implant survival of 98% after 5 and 7,5 years with revision for any reason as endpoint.

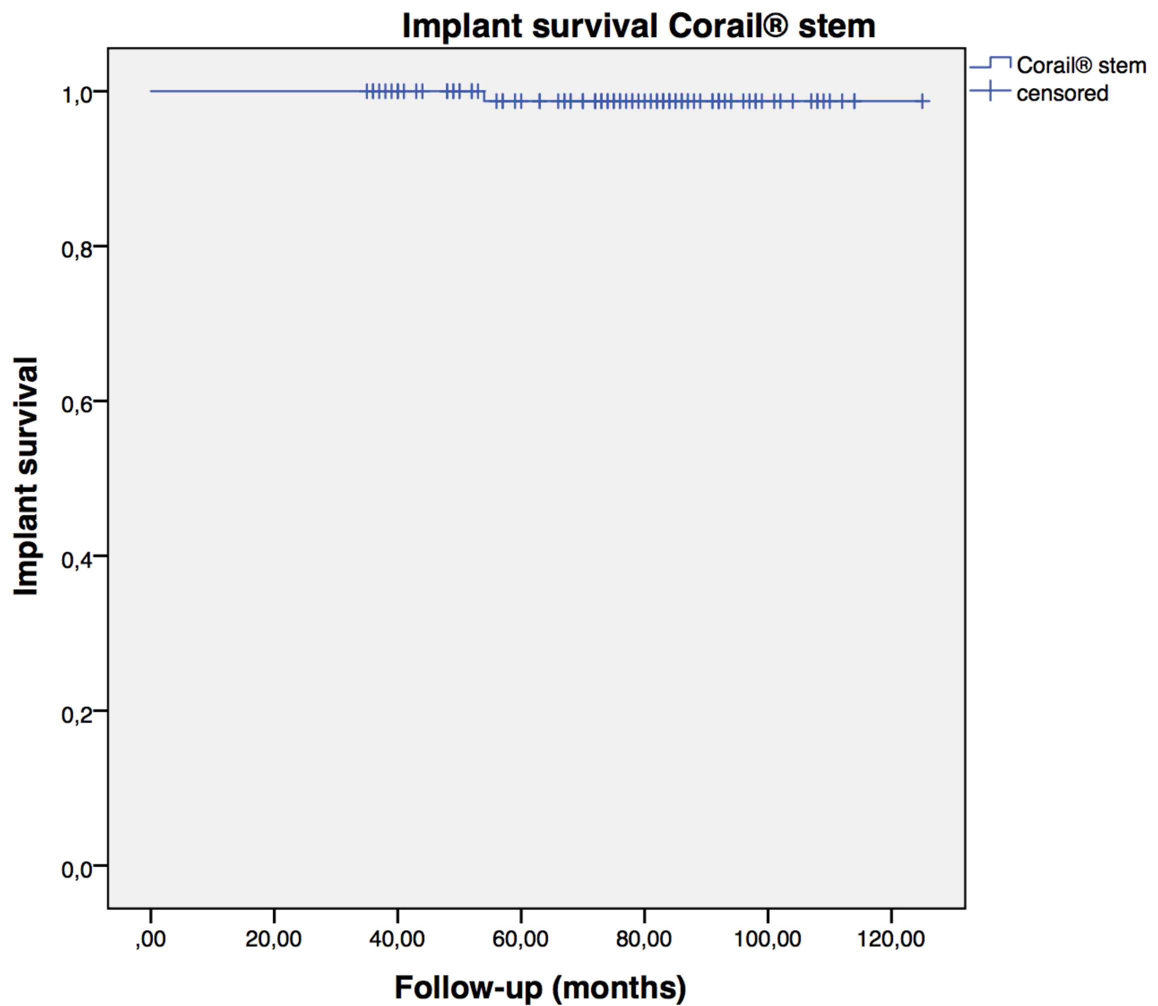

Figure 26: Implant survival for aseptic loosening

With aseptic loosening as endpoint, the Kaplan-Meier curve showed an implant survival of 98,9% after 5 and 7,5 years.

8.2. X-ray analysis

<u>Heterotopic Ossification</u>

HO occurred in 13 cases (13%), overall. Results can be seen in table 6.

Table 6: Distribution of HO according to the Brooker classification

	Class 1	Class 2	Class 3	Class 4
Female	6	-	1	-
Male	5	-	1	-
Total	11	-	2	-

<u>Radiolucent lines according to Gruen and Johnston</u>

Zone 1 (33 cases, 39%) and zone 8 (27 cases, 32%) according to Gruen and Johnston were affected the most by radiolucent lines, followed by zone 14 (15 cases, 18%).

In 22 patients, zone 1 and zone 8 appeared together. Furthermore, zone 1, 8 and 14 occurred together in 12 patients.

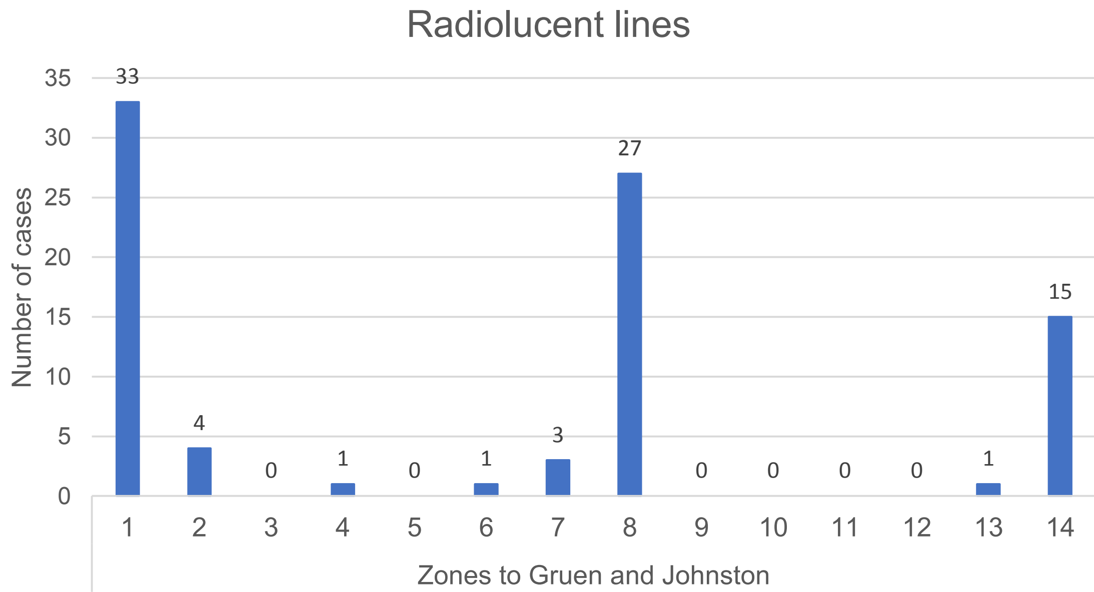

Figure 27: Distribution of radiolucent lines according to the zones of Gruen and Johnston

Stress shielding

Stress shielding occurred in 3 cases (3%), in 2 female and in 1 male patient after a mean follow up of 20 months (range: 8 - 31).

Irregular periprosthetic bone resorption (osteolysis)

Osteolysis was found in 1 female patient (1%). It occurred around the stem of the prosthesis 86 months after implantation.

8.3. MediCAD classic® (Hectec GmbH, Altdorf, Germany)

Leg length

The mean preoperative length discrepancy added up to 3,9 mm (standard deviation: 5,2) with a range from 0 to 20 mm. The mean postoperative leg length discrepancy was 4,3 mm (standard deviation: 5,2) with a range from 0 to 13 mm.

Acetabular offset

The mean preoperative acetabular offset was 35.7 mm (standard deviation: 5,9) with a range from 27 to 68 and changed to a mean postoperative offset of 31,7 mm (standard deviation: 3,7) with a range from 26 to 51.

Femoral offset

The mean preoperative femoral offset measured 39.1 mm (standard deviation: 8,6) with a range from 13 to 60 and improved to a more physiological offset of 43.3 mm (standard deviation: 5,9) with a range from 30 to 55 postoperatively.

Anteversion and inclination of the cup

The average anteversion of the Pinnacle® cup measured 20,2° (standard deviation: 4) with a range from 9,5 to 28,7. The mean inclination measured 44,3° (standard deviation: 6,8) with a range from 30 to 62,6. There was no cup with less than 9,5° of anteversion and no cup with a steeper inclination of 62,6°.

CCD-angle

The mean preoperative CCD-angle was 125,6° (standard deviation: 7,2) with a range from 102,3° to 141,4° and changed to average 135° postoperatively (standard deviation: 2,6) with a range from 129,2° to 142,8°.

8.4. EBRA-FCA® (University of Innsbruck, Institute for Basic Sciences in Engineering Unit Geometry and CAD, Austria)

The highest migration, which was measured during the time of follow up, was 1,5 mm in three prostheses. As mentioned before, the accuracy of EBRA-FCA® was stated with +/-1,5 mm [32].

Table 7: Migration of the stem during time of follow up

Years	0,5	1	2	3	4	5	6	7	8
Mean Subsidence mm	0,26	0,34	0,51	0,56	0,53	0,60	0,46	0,44	0,60
n	73	88	36	39	35	34	27	35	26

The mean stem subsidence after six months was 0,26 mm, 0,34 mm after one year, 0,51 mm after two years, 0,56 mm after three years, 0,53 mm after four years and increased to 0,6 mm after five years. Then the subsidence decreased to 0,46 mm after six and to 0,44 mm after seven years. After that, the subsidence rose again to 0,6 mm after 8 years.(Fig. 28)

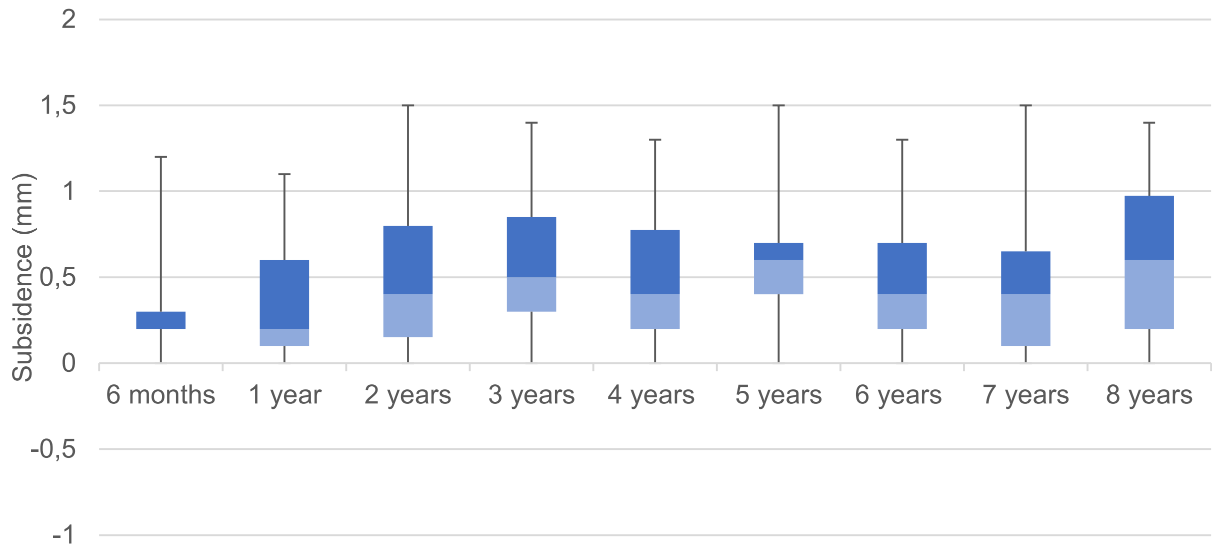

Figure 28: Box plots of stem's subsidence in mm

9. Discussion

The results of the collarless Corail® stem with the 36 mm CoC bearing in relation to the occurrence of subsidence, radiolucent lines and implant survival showed convincing results during the follow-up of 6,3 years. No significant migration occurred during this time. 2 revisions had to be performed, which reflects an implant survival of 98 % after 5 and 7,5 years. These results conform to the data from other studies. The implant survival was stated with 98 % after 10 years and 97 % after 15 years due to the Norwegian Arthroplasty Register [33]. According to the 2016 annual report of the Australian Orthopaedic Association the survival rate was stated with 97 % after 5 years and 95 % after 10 years [34]. The 2016 annual report of the National Joint registry showed an implant survival rate of 98 % after 5 years, 97 % after 7 years and 96 % after 10 years [35].
However, there are some issues, which have to be discussed in the following:

<u>Results of the migration analysis in comparison to other studies</u>

The highest subsidence, which was measured in this study, was 1,5 mm in 3 prostheses (3%) during the whole time of follow-up. The accuracy of the EBRA-FCA method was stated with 1,5 mm [32]. Al-Najjim et al. reported a subsidence of more than 3 mm in 10,9 % of all collarless Corail® KS stems in their study with a follow-up of 1 year. This migration appeared within the first 6 - 8 weeks postoperatively [36]. This trend was confirmed by other authors, who also recognized that the majority of the subsidence was found in the first six months following THR [37, 38, 39]. This observation could not be confirmed in this current study. Campbell et al. showed a subsidence of 0,73 mm (range: 3,46 – 0,26) after 6 months, 0,62 mm (range: 3,66 – 0,35) after 1 year and 0,58 mm (range: 0,23 – 3,71) 2 years after implanting the collarless Corail® KS stem, by using Radiostereometric analysis [38]. We measured a mean subsidence of 0,26 mm (range: 0 – 1,2) after 6 months, 0,34 mm (range: 0 – 1,1) after 1 year and 0,51 mm (range: 0 - 1,5) after 2 years.

Collarless or collared Corail® stem

Among experts, the opinion on the importance of an additional collar in the femoral stem differs. In general, the use of a collar for cementless stems is not common. In literature, only few data is available, dealing with the use of a collar in cementless stems [40].
The theoretical advantages of a collar are: An enhanced rotational stability based on the fact that the collar reduces the lever, which leads to a bigger torque. The collar inhibits rotational instability by impinging on the calcar. Further theoretical advantages are reduced subsidence and lower risk of calcar fracture propagation. It is suspected that the collar seals the femur, which delimitates the infiltration of polyethylene wear debris into the femoral canal [40, 41]. According to Demey et al. the collar provides a higher immediate stability compared to collarless options, because of a higher resistance towards horizontal and vertical force [42]. Another advantage is that there is no necessity to enlarge the size of the stem to achieve an increased primary stability, due to the greater immediate stability when using a collar, as stated above [40]. However, Jacquot and Rollier performed a study in which collared and collarless Corail® stems were compared with each other. No significant difference regarding the survival rate and the radiological- and clinical outcome between these two stem types were apparent [40]. The collared Corail® stem reveals no long term benefit in comparison to the collarless [41]. All the advantages, which the collar owns, are short term in arranging an enhanced primary stability, which is required for secondary integration. However, the collar has no adverse radiological effect. Calcar resorption appears commonly by using the collared stem, but no more common than with the collarless stem [41].

The CoC bearing in comparison to other bearing options

The CoC bearing owns the lowest wear rate and beside this, it is the hardest bearing option. The wear of the BIOLOX® delta bearing, which was used in the study, amounts to less than 0,5 mm^3/ million cycles under microseparation and rim wear conditions [43,44]. In comparison to this, ceramic-on-metal (CoM) bearings own a wear rate of 1 mm^3/ million cycles under microseparation conditions, MoM bearings between 0,1 to 1 mm^3/ million cycles, depending on the lubrication conditions, cross-

linked polyethylene inserts between 5 to 10 mm^3/ million cycles and conventional polyethylene inserts between 25 to 40 mm^3/ million cycles, depending on which material is used for the femoral head [43].
However, there are also some concerns when using CoC bearings. Fracturing of the acetabular component or chipping of the insert during implantation or due to rim loading was reported. Another negative concomitant is the squeaking phenomenon, which also occurred in one patient in this study [43].
In addition to the CoC bearing, there are a couple of other bearing options like ceramic-on-polyethylene (CoP), metal-on-polyethylene (MoP) and CoM. According to Fisher et al., CoP and MoP are probably the best choices for most patients. For very active patients, CoC or CoM bearings are the better choice, because of much lower wear rates in comparison with cross-linked polyethylene [43, 45]. However, a recent study from Hill et al. advises against the use of CoM bearings, because of unexpected high blood ion levels and the frequently presence of RLL [46].

The large 36 mm femoral head in comparison to smaller heads

In order to increase stability and enhance function after primary THR, the current trend using greater femoral head sizes could be visible [47]. There has been an increase in the use of 36 mm femoral heads from 5 % of all performed THR in 2005 to 35 % in 2011, according to the data of the National Joint Registry of England, Wales and Northern Ireland [48, 49].
According to Girard, larger femoral heads possess a lower risk for dislocation than smaller heads. Beside this, there is an improvement in the range of motion and a delay in cam type impingement conforming to Girard [49]. However, there are also critical studies concentrating on the use of femoral heads. A large femoral head, which is used in a CoC bearing, arranges a better flexion, but early complication rate and functional outcome remain the same in comparison to smaller femoral heads at 1 to 3 years of follow-up, conforming to Lu et al. [50]. Lachiewicz et al. described a dislocation rate of 4 % for 36 mm femoral heads 1 year after operation. After 5 years, no additional dislocation occurred. In comparison to these results, the dislocation rate in smaller femoral heads is described between 6 and 23 % [51].

Cementless or cemented stem

There has been a trend towards the use of cementless implant design in the last years. In 2003 60,4 % of all THR, which were primary implanted in England, Wales and Northern Ireland, were cemented in comparison to 16,8%, which were cementless. In 2016 only 35,5 % of all primary implanted THR were cemented, but 39,1% were cementless [35]. In Australia, the use of the cementless fixation technique in primary implanted THR changed from 51,3 % in 2003 to 63,3 % in 2016. The Cemented fixation technique in primary implanted THR decreased in the same period of time from 13,9 % in 2003 to 3,7 % in 2016 according to the Australian Orthopaedic Association [34]. The issue, whether cementless or cemented fixation is superior, is still discussed controversially.
The cemented femoral stem reveals good results, especially in older patients with osteoporotic bones. The cement fixation appears by "microinterlock with endosteal bone" [35 p194]. In younger patients cemented stems are accompanied by higher rates of aseptic loosening and osteolysis [37].
The cementless fixation technique is based on biological fixation by bone ingrowth into the stem. This biological fixation between the stem surface and the endosteal bone purposes to reduce the occurrence of aseptic loosening [37, 52]. The cementless fixation technique is perfect for young active male patients.
However, there are some studies, which reveal that the cementless fixation technique in patients over 65 years with inferior bone quality, leads to good results [37].

Limitations

The present study has certain limitations. First of all, the retrospective design of this study is one factor. The exposure dates and the number of radiographs vary greatly from patient to patient. A prospective design would be the better choice to receive more comparable data.
Another point is the amount of surgeons, who performed the THR, which were included in this study. 15 surgeons participated. Considering a better comparability it would be better, if less surgeons performed all THR.

The patient collective varied significantly, regarding their age. The youngest patient was 21, whereas the oldest was 81 years old. However the distribution between sex was relatively balanced. The study included 48 women and 46 men.
The EBRA-FCA® is not the best method regarding precision for measuring the subsidence of the stem. The RSA is the most reliable technique. But facing the effort and costs of both methods, EBRA-FCA® is a good choice. Furthermore you need tantalum markers implanted for using the RSA method, which is impossible in this retrospective study.

Conclusion

In conclusion, the collarless Corail® stem with the 36 mm CoC bearing performed well during the mean follow-up of 6,3 years. The results of the radiological analysis are encouraging with regards to migration and osseointegration. Subsidence data show less than 0.7 millimeters six years after primary implantation with no stem migrated more than 1,5 mm.
These results confirm our decision to continue implanting the collarless Corail® stem with the large 36 mm CoC bearing at our department.

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